

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants:	Benjamin OSHLACK et al.
Serial No.:	To Be Assigned
Filed:	Herewith
For:	<b>CONTROLLED RELEASE HYDROCODONE FORMULATIONS</b>

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
Alexandria, VA 22313-1450  
Mail Stop: Patent Application

September 11, 2003

Sir:

In accordance with the provisions of 37 C.F.R. § 1.97, Applicants enclose herewith the Information Disclosure Statement and accompanying Form PTO-1449 (14 sheets) submitted in the parent case; U.S. Application Serial No. 10/016,651, on September 25, 2002. Applicants also enclose herewith the Form PTO-1449 (1 sheet) submitted in the Information Disclosure Statement in U.S. Application Serial No. 10/016,651, on March 18, 2003.

Pursuant to 37 CFR 1.98(d), copies of the references of record in the parent application are not enclosed. Copies of the Exhibits to the September 25, 2002 Information Disclosure Statement are also not enclosed as they are of record in the parent application. If it is determined that any of the references or Exhibits are not of record in the parent application, the Examiner is requested to contact the undersigned so that a copy can be forwarded.

It is respectfully requested that the references cited in the accompanying Form PTO-1449 be considered and made of record. It is respectfully submitted that the pending claims are patentable over all of the references made of record at this time.

The Examiner's attention is also directed to the following copending patent applications and issued U.S. Patents:

U.S. Patent Application Serial No. 10/392,586, filed March 20, 2003, entitled "Orally Administrable Opioid Formulations Having Extended Duration of Effect," which is a continuation of U.S. Application Serial No. 09/891,882, filed June 26, 2001, entitled "Orally Administrable Opioid Formulations Having Extended Duration of Effect," now Patent No. 6,572,885, issued on June 3, 2003, which is a continuation of Serial No. 09/390,719 filed September 7, 1999, entitled "Orally Administrable Opioid Formulations Having Extended Duration of Effect," now U.S. Patent No. 6,294,195, which is a continuation of U.S. Application Serial No. 08/508,246, filed July 27, 1995, now U.S. Patent No. 5,968,551.

U.S. Patent Application Serial No. 10/162,136 filed June 4, 2002, entitled "Methods of Treating Pain by Administering 24 Hour Oral Opioid Formulations Exhibiting Rapid Rate of Initial Rise of Plasma Drug Level", which is a continuation of U.S. Patent Application Serial No. 08/938,898, filed September 26, 1997, entitled "Method of Treating Pain by Administering 24 Hour Oral Opioid Formulations Exhibiting Rapid Rate of Initial Rise of Plasma Drug Level," Abandoned, which is a continuation of Serial No. 08/578,668, filed July 22, 1996, now issued U.S. Patent No. 5,672,360, which is a continuation-in-part of Serial No. 08/156,468 filed November 23, 1993, issued as U.S. Patent No 5,478,577.

U.S. Application Serial No. 09/304,694 filed May 4, 1999, entitled "Methods of Treating Pain by Administering 24 Hour Oral Opioid Formulations Exhibiting Rapid Rate of Initial Rise of Plasma Drug Level" which is a continuation of Serial No. 08/938,898 filed September 26, 1997, entitled "Method of Treating Pain by Administering 24 Hour Oral Opioid Formulations Exhibiting Rapid Rate of Initial Rise of Plasma Drug Level," Abandoned, which is a continuation of Serial No. 08/578,668 filed July 22, 1996, issued as U.S. Patent No. 5,672,360,

which is a continuation-in-part of Serial No. 08/156,468 filed November 23, 1993, issued as U.S. Patent No 5,478,577.

U.S. Patent Application Serial No. 09/624,530, filed July 24, 2000, entitled "Method of Treating Humans with Opioid Formulations Having Extended Controlled Release," which is a continuation of U.S. Application Serial No. 08/838,368 filed April 8, 1997, now U.S. Patent No. 6,143,322, which is a continuation of U.S. Patent Application Serial No. 08/677,797, filed July 10, 1996, now abandoned, which is a continuation of U.S. Patent Application Serial No. 08/561,829, filed November 27, 1995, now U.S. Patent No. 5,958,459, which is a continuation of U.S. Patent Application Serial No. 08/086,248, filed July 1, 1993, now abandoned.

U.S. Patent Application Serial No. 09/632,718 filed August 4, 2000, entitled "Opioid Formulations Having Extended Controlled Release," which is a continuation of U.S. Application Serial No. 09/225,959, filed January 6, 1999, now U.S. Patent No. 6,103,261, which is a continuation of Serial No. 08/561,829, filed November 27, 1995, now U.S. Patent No. 5,958,459, which is a continuation of U.S. Patent Application Serial No. 08/086,248, filed July 1, 1993, now abandoned.

U.S. Application Serial No. 09/702,283, filed October 30, 2000, entitled "Controlled Release Hydrocodone Formulations", still pending, which claims benefit of U.S. Provisional Patent Application No. 60/162,541, filed October 29, 1999.

Pursuant to 37 C.F.R. § 1.98 (a)(2)(iii) the Examiner's attention is directed to Exhibit A attached herewith which contains the following:

(i) pending claims of pending application serial no. 10/392,586, which has the same specification as U.S. Patent No. 5,968,551, listed as reference MF on the enclosed Form PTO 1449;

(ii) specifications and claims of pending application serial no and 09/702,283;

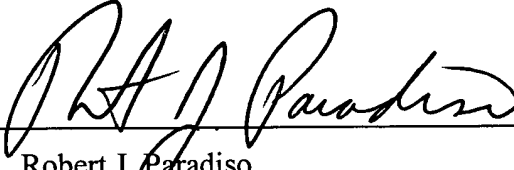
(iii) claims of pending application serial nos. 09/304,694 and 10/162,136, which have the same specification as U.S. Patent No. 5,672,360, listed as reference DD on the enclosed Form PTO-1449;

(iv) claims of pending application serial no. 09/624,530, which has the same specification as U.S. Patent No. 5,958,459, listed as reference GC on the enclosed Form PTO 1449;

(v) claims of pending application serial no. 09/632,718, which has the same specification as U.S. Patent No. 6,103,261, listed as reference GD on the enclosed Form PTO 1449.

No fee is believed to be due for the submission of this Information Disclosure Statement as it is filed under 37 C.F.R. §1.97(b), before the mailing of a first Office Action on the merits or within three (3) months of the actual filing date. The Commissioner is authorized to charge any additional fee or credit any overpayment to our Deposit Account 50-0552.

Respectfully Submitted,  
DAVIDSON, DAVIDSON & KAPPEL, LLC

By:   
Robert J. Paradiso  
Reg. No. 41,240

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**UNITED STATES PATENT AND TRADEMARK OFFICE**

Re: Application of: Benjamin OSHLACK, et al.  
Serial No.: 10/016,651  
Filed: October 30, 2001  
For: **CONTROLLED RELEASE HYDROCODONE  
FORMULATIONS**

**INFORMATION DISCLOSURE STATEMENT**

Assistant Commissioner for Patents  
Washington, D.C. 20231

September 25, 2002

S i r:

In accordance with the provisions of 37 C.F.R. § 1.97(b), applicants hereby make of record the following: Exhibit A, Form PTO-1449 (14 pages) and the references cited therein.

Attached as Exhibit A is the Court of Appeals for the Federal Circuit Decision and Opinion for the litigation involving the Assignee's U.S. Patent No. 5,672,360 (cited as reference MK in the PTO 1449 Form). It is respectfully requested that this attachment be considered and made of record.

Additionally the Examiner's attention is directed to the following copending patent applications:

Serial No. 09/891,882, filed June 26, 2001, entitled "Orally Administrable Opioid Formulations Having Extended Duration of Effect," which is a continuation of Serial No. 09/390,719 filed September 7, 1999, entitled "Orally Administrable Opioid Formulations Having Extended Duration of Effect," which is a continuation of U.S. Application Serial No. 08/508,246, filed July 27, 1995, now U.S. Patent No. 5,968,551.

Serial No. 09/304,694 filed May 4, 1999, entitled "Methods of Treating Pain by Administering 24 Hour Oral Opioid Formulations Exhibiting Rapid Rate of Initial Rise of

Plasma Drug Level” is a continuation of Serial No. 08/938,898 filed September 26, 1997, entitled “Method of Treating Pain by Administering 24 Hour Oral Opioid Formulations Exhibiting Rapid Rate of Initial Rise of Plasma Drug Level,” which is a continuation of Serial No. 08/578,668 filed July 22, 1996, issued as the 5,672,360 patent, which is a continuation-in-part of Serial No. 08/156,468 filed November 23, 1993, issued as U.S. Patent No 5,478,577.

Serial No. 09/624,530, filed July 24, 2000, entitled “Method of Treating Humans with Opioid Formulations Having Extended Controlled Release,” which is a continuation of U.S. Application Serial No. 08/838,368 filed April 8, 1997, now U.S. Patent No. 6,143,322, which is a continuation of U.S. Patent Application Serial No. 08/677,797, filed July 10, 1996, now abandoned, which is a continuation of U.S. Patent Application Serial No. 08/561,829, filed November 27, 1995, now U.S. Patent No. 5,958,459, which is a continuation of U.S. Patent Application Serial No. 08/086,248, filed July 1, 1993, now abandoned.

Serial No. 09/632,718 filed August 4, 2000, entitled “Opioid Formulations Having Extended Controlled Release,” which is a continuation of U.S. Application Serial No. 09/225,959, filed January 6, 1999, now U.S. Patent No. 6,103,261, which is a continuation of Serial No. 08/561,829 described above.

Serial No. 09/702,283, filed on October 30, 2000, entitled “Controlled Release Hydrocodone Formulations,” still pending, which claims benefit of U.S. Provisional Patent Application No. 60/162,541, filed on October 29, 1999.

It is respectfully requested that Exhibit A, the PTO 1449 Form (14 pages) and references cited therein be considered and made of record.

No fee is believed to be due for the submission of this Information Disclosure Statement as it is filed under 37 C.F.R. §1.97(b), before the mailing of a first Office Action on the merits or within three (3) months of the actual filing date. The Commissioner is authorized to charge any additional fee or credit any overpayment to our Deposit Account 50-0552.

Respectfully submitted,

DAVIDSON, DAVIDSON & KAPPEL, LLC

By: 

Robert J. Paradiso  
Reg. No. 41,240

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New York, New York 10018  
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FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE				ATTY. DOCKET NO.: 200.1138 US		SERIAL NO.: 10/016,651						
<b>LIST OF PRIOR ART CITED BY APPLICANT</b> (Use several sheets if necessary)						APPLICANT(S): Benjamin OSHLACK, et al.								
						FILING DATE: October 30, 2001		GROUP: 1615						
U.S. PATENT DOCUMENTS														
*EXAMINER INITIAL	AA	DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	AA	3	6	3	4	5	8	4	01/11/72	Poole	424	21		
	AB	3	8	4	5	7	7	0	11/05/74	Theeuwes, et al.	128	260		
	AC	3	8	7	0	7	9	0	03/11/75	Lowey, et al.	424	19		
	AD	3	9	1	6	8	9	9	11/04/75	Theeuwes, et al.	128	260		
	AE	4	3	7	7	5	6	8	03/22/83	Chopra	424	31		
	AF	4	3	8	5	0	7	8	05/24/83	Onda, et al.	427	3		
	AG	4	3	8	9	3	9	3	06/21/83	Schor, et al.	424	19		
	AH	4	4	8	3	8	4	7	11/20/84	Augart	424	22		
	AI	4	5	2	0	1	7	2	05/28/85	Lehmann, et al.	525	369		
	AJ	4	5	4	8	9	9	0	10/22/85	Mueller, et al.	525	123		
	AK	4	5	5	7	9	2	5	12/10/85	Lindahl, et al.	424	19		
FOREIGN PATENT DOCUMENTS														
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	AL	0	2	3	5	9	8	6	09/09/87	EPO (A1)	A61K	9/16		
	AM	0	6	6	5	0	1	0	08/02/95	EPO (A1)	A61K	9/26		
	AN	0	2	5	3	1	0	4	01/20/88	EPO (A1)	A61K	9/00		
	AO	0	3	8	8	9	5	4	09/26/90	EPO (A2)	A61K	9/14		
	AP	0	4	1	5	6	9	3	03/06/91	EPO (A1)	A61K	37/02		
	AQ	0	5	3	4	6	2	8	03/31/93	EPO (A1)	A61K	31/485		
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)														
	AR	Abraham Sunshine et al., "Analgesic Oral Efficacy of Tramadol Hydrochloride in Postoperative Pain," <u>Clin. Pharmacol. Ther.</u> , Vol. 51, June 1992, pages 740-746.												
	AS	E.Beubler, "Medikamentöse Schmerztherapie: Kriterien, Möglichkeiten, Risiken," <u>Therapiewoche Österreich</u> , 7,2 (1992), pages 1-15, English translation.												
	AT	Gourlay, et al., "Influence of a High-Fat Meal On The Absorption of Morphine From Oral Solutions," <u>Clin. Pharmacol. Ther.</u> , Vol. 46, October 1989, pages 463-468												
EXAMINER										DATE CONSIDERED				
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.														

FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE				ATTY. DOCKET NO.: 200.1138US		SERIAL NO.: 10/016,651						
<b>LIST OF PRIOR ART CITED BY APPLICANT</b>  (Use several sheets if necessary)						APPLICANT(S): Benjamin OSHLACK, et al.								
						FILING DATE: October 30, 2001		GROUP: 1615						
U.S. PATENT DOCUMENTS														
*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	BA	4	7	2	8	5	1	3	03/01/88	Ventouras	424	461		
	BB	4	7	9	7	4	1	0	01/10/89	El-Fakahany	514	356		
	BC	4	8	0	6	3	3	7	02/21/89	Snipes, et al.	71	65		
	BD	4	8	2	8	8	3	6	05/09/89	Elger, et al.	424	419		
	BE	4	8	3	4	9	8	4	05/30/89	Goldie, et al.	424	488		
	BF	5	0	6	8	1	1	0	11/26/91	Fawzi, et al.	424	461		
	BG	4	8	4	4	9	0	7	07/04/89	Elger, et al.	424	465		
	BH	5	0	1	9	3	9	7	05/28/91	Wong, et al.	424	473		
	BI	4	9	8	3	7	3	0	01/08/91	Domeshek, et al.	536	69		
	BJ	5	4	5	6	9	2	3	10/10/95	Nakamichi, et al.	424	489		
	BK	5	4	6	0	8	2	6	10/24/95	Merrill, et al.	424	470		
FOREIGN PATENT DOCUMENTS														
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	BL	0	5	3	5	8	4	1	04/07/93	EPO (A1)	A61K	31/485		
	BM	0	5	4	6	6	7	6	06/16/93	EPO (A1)	A61K	31/60		
	BN	0	5	4	8	4	4	8	06/30/93	EPO (A1)	A61K	9/50		
	BO	0	5	8	0	8	6	0	02/02/94	EPO (A1)	A61K	9/14		
	BP	2	1	7	8	3	1	3	02/11/87	Great Britain (A)	A61K	9/14		
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)														
	BQ	Geoffrey K. Gourlay, et al. "The Reproducibility of Bioavailability of Oral Morphine from Solution Under Fed and Fasted Conditions," Journal of Pain and Symptoms Management, Vol. 6., No. 7, October 1991, Pages 431-436												
	BR	Robert F. Kaiko, et al., "Controlled-Release Morphine Bioavailability (MS Contin Tablets) in the Presence and Absence of Food," The Hospice Journal, Vol. 6(4) 1990, pages 17-30.												
	BS	Kaiko, et al., "A Single-Dose Study of The Effect of Food Ingestion and Timing of Dose Administration On The Pharmacokinetic Profile of 30-mg Sustained-Release Morphine Sulfate Tablets," <u>Current Therapeutic Research</u> , Vol. 47, No. 5, May 1990, pages 869-878.												
EXAMINER										DATE CONSIDERED				
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.														

FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: 200.1138US		SERIAL NO.: 10/016,651								
<b>LIST OF PRIOR ART CITED BY APPLICANT</b>  (Use several sheets if necessary)				APPLICANT(S): Benjamin OSHLACK, et al.										
				FILING DATE: October 30, 2001		GROUP: 1615								
U.S. PATENT DOCUMENTS														
*EXAMINER INITIAL	CA	DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	CA	5	5	0	8	0	4	2	04/16/96	Oshlack, et al.	424	468		
	CB	5	5	4	9	9	1	2	08/27/96	Oshlack, et al.	424	468		
	CC	5	6	0	1	8	4	2	02/11/97	Barholomaeus	424	464		
	CD	5	5	2	0	9	3	1	05/28/96	Persson, et al.	424	473		
	CE	5	1	2	2	3	8	4	06/16/92	Paradissis, et al.	424	451		
	CF	4	8	6	1	5	9	8	08/29/89	Oshlack	424	468		
	CG	5	4	1	1	7	4	5	05/02/95	Oshlack, et al.	424	456		
	CH	5	5	0	0	2	2	7	03/19/96	Oshlack, et al.	424	476		
	CI	5	5	8	0	5	7	8	12/03/96	Oshlack, et al.	424	468		
	CJ	5	4	7	2	7	1	2	12/05/95	Oshlack, et al.	424	480		
	CK	5	3	7	8	4	7	4	01/03/95	Morella, et al.	424	469		
FOREIGN PATENT DOCUMENTS														
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	CL	W O	92	0	1	4	4	6	02/06/92	PCT (A1)	A61K	9/50		
	CM	W O	92	0	6	6	7	9	04/30/92	PCT (A1)	A61K	9/16		
	CN	W O	93	0	4	6	7	5	03/18/93	PCT (A1)	A61K	31/16		
	CO	W O	93	1	8	7	5	3	09/30/93	PCT (A1)	A61K	9/16		
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)														
	CP	Yokokawa N., et al., "Relationship between plasma concentration of morphine and analgesic effectiveness," <u>Postgrad Med J.</u> (1991) 67 (Suppl. 2) pages S50-S54.												
	CQ	Physicians Desk Reference 1994, 48 <sup>th</sup> Edition, pages 1821-1824.												
	CR	D.L. Munday, et al., "Changes in Drug Release Rate 2, Effect of Temperature and Relative Humidity on Polymeric Film Coatings," 5 <sup>th</sup> Cong. Int. Tech. Pharm., 1989, Vol. 2, pp. 55-60.												
EXAMINER										DATE CONSIDERED				
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.														

FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE				ATTY. DOCKET NO.: 200.1138 US		SERIAL NO.: 10/016,651						
<b>LIST OF PRIOR ART CITED BY APPLICANT</b>  (Use several sheets if necessary)						APPLICANT(S): Benjamin OSHLACK, et al.								
						FILING DATE: October 30, 2001		GROUP: 1615						
<b>U.S. PATENT DOCUMENTS</b>														
*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	DA	4	9	7	0	0	7	5	11/13/90	Oshlack	424	451		
	DB	5	6	5	6	2	9	5	08/12/97	Oshlack, et al.	424	468		
	DC	5	6	7	0	1	7	2	09/23/97	Buxton, et al.	424	495		
	DD	5	6	7	2	3	6	0	09/30/97	Sackler, et al.	424	490		
	DE	5	5	9	3	6	9	5	01/14/97	Merrill, et al.	424	480		
	DF	5	6	6	7	8	0	5	09/16/97	Merrill, et al.	424	473		
	DG	4	9	9	0	3	4	1	02/05/91	Goldie, et al.	424	484		
	DH	5	2	7	3	7	6	0	12/28/93	Oshlack, et al.	424	480		
	DI	4	8	6	1	5	9	8	08/29/89	Oshlack	424	468		
	DJ	4	8	4	4	9	0	9	07/04/89	Goldie	424	480		
	DK	5	2	6	6	3	3	1	11/30/93	Oshlack, et al.	424	468		
<b>FOREIGN PATENT DOCUMENTS</b>														
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	DL	2	1	7	0	1	0	4	07/30/86	United Kingdom (A)	A61K	9/58		
	DM	WO	94	2	2	4	3	1	10/13/94	PCT (A1)	A61K	9/20		
	DN	WO	96	0	0	0	6	6	01/04/96	PCT (A1)	A61K	31/485		
	DO	WO	96	0	1	6	2	9	01/25/96	PCT (A1)	A61K	31/485		
	DP	WO	94	0	5	2	6	2	03/17/94	PCT (A1)	A61K	9/16		
<b>OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)</b>														
	DQ	A Protocol for a clinical study entitled "A Randomized, Double-Blind, Parallel-Group Study comparing the Efficacy and Safety of Kapanol® to MS Contin® in the Management of Patients with Moderate to Severe Cancer Pain" ("the Protocol"). The date of the Protocol is indicated as February 10, 1992 and it bears COD No. 14556. The sponsor of the study is indicated to be Faulding Pharmaceuticals, and Australian company.												
	DR	Certain Patients Diary Cards, Drug Disposition Records, Case Reports Forms and listing which apparently correlates patient randomization number with the treatment of dosing regimen assigned to each patient.												
	DS	Patient consent forms, apparently for four study participants.												
EXAMINER										DATE CONSIDERED				
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.														

FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE				ATTY. DOCKET NO.: 200.1138US		SERIAL NO.: 10/016,651						
<b>LIST OF PRIOR ART CITED BY APPLICANT</b>  (Use several sheets if necessary)						APPLICANT(S): Benjamin OSHLACK, et al.								
						FILING DATE: October 30, 2001		GROUP: 1615						
<b>U.S. PATENT DOCUMENTS</b>														
*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	EA	4	8	3	4	9	8	5	05/30/89	Elger, et al.	424	488		
	EB	5	0	7	1	6	4	6	12/10/91	Malkowska, et al.	424	497		
	EC	5	2	0	2	1	2	8	04/13/93	Morella, et al.	424	469		
	ED	5	1	7	8	8	6	8	01/12/93	Malmqvist, et al.	424	490		
	EE	5	1	3	3	9	7	4	07/28/92	Paradissis, et al.	424	480		
	EF	4	6	0	0	6	4	5	07/15/86	Ghebre-Sellassie, et al.	428	403		
	EG	4	7	0	8	8	7	4	11/24/87	De Haan, et al.	424	470		
	EH	5	0	2	4	8	4	2	06/18/91	Edgren, et al.	424	473		
	EI	5	1	6	9	6	4	5	12/08/92	Shukla, et al.	424	499		
	EJ	5	2	8	3	0	6	5	02/01/94	Doyon, et al.	424	467		
	EK	5	3	2	1	0	1	2	06/14/94	Mayer, et al.	514	25		
<b>FOREIGN PATENT DOCUMENTS</b>														
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	EL	WO	96	1	4	0	5	8	05/17/96	PCT (A1)	A61K	9/14		
	EM	0	5	3	2	3	4	8	03/17/93	EPO (A2)	A61K	31/35		
	EN	0	6	3	6	3	7	0	02/01/95	EP (B1)	A61K	31/485		
	EO	9	0	4	7	7	3	2	07/12/90	Australia				
	EP	9	3	4	1	6	5	4	02/16/95	Australia				
<b>OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)</b>														
	EQ	Investigator agreements between the study organizers and certain of the principal investigators.												
EXAMINER										DATE CONSIDERED				
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<b>LIST OF PRIOR ART CITED BY APPLICANT</b>  (Use several sheets if necessary)				APPLICANT(S): Benjamin OSHLACK, et al.										
				FILING DATE: October 30, 2001		GROUP: 1615								
<b>U.S. PATENT DOCUMENTS</b>														
*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	FA	4	6	0	9	5	4	2	09/02/86	Panoz, et al.	424	19		
	FB	5	2	0	6	0	3	0	04/27/93	Wheatley, et al.	424	490		
	FC	5	2	1	9	5	7	5	06/15/93	Van Bommel, et al.	424	490		
	FD	5	2	4	8	5	1	6	09/28/93	Wheatley, et al.	427	3		
	FE	5	2	5	8	4	3	6	11/20/93	Wheatley, et al.	524	388		
	FF	5	3	8	4	1	3	0	01/24/95	Kamada	424	461		
	FG	5	6	3	7	3	2	0	06/10/97	Bourke, et al.	424	489		
	FH	5	2	8	6	4	9	3	02/15/94	Oshlack, et al.	424	468		
	FI	5	0	0	7	7	9	0	04/16/91	Shell	424	451		
	FJ	5	3	3	0	7	6	6	07/19/94	Morella, et al.	424	490		
	FK	5	6	8	1	5	8	5	10/28/97	Oshlack, et al.	424	494		
<b>FOREIGN PATENT DOCUMENTS</b>														
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	FL	0	2	7	1	1	9	3	06/15/88	EPO (B1)	A61K	31/485		
	FM	0	0	9	7	5	2	3	01/04/84	EPO (A2)	A61K	9/26		
	FN	WO	93	1	0	7	6	5	06/10/93	PCT	A61K	9/22		
	FO	0	3	7	7	5	1	8	07/11/90	EPO (A2)	A61K	9/52		
	FP	WO	94	0	3	1	6	1	02/17/94	PCT	A61K	9/52		
<b>OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)</b>														
	FQ	Abstracts from the Twelfth Annual Congress of the Oncology Nursing Society, May 1987, In Clinical Nursing Forum Supplement Vol. 14 (2), p112, 1987.												
	FR	J. Lapin et al., "Cancer Pain Management with a Controlled Release Oral Morphine Preparation," <u>Pain and Symptom Manag.</u> , Vol. 4 (3), pp.146-151, 1989.												
	FS	J. Lapin et al., "Guidelines for Use of Controlled Release Oral Morphine in Cancer Pain Management," <u>Cancer Nursing</u> , Vol. 12 (4), pp. 202-208, (1989).												
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*EXAMINER INITIAL	GA	GB	GC	GD	GE	GF	GG	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
								5 4 7 8 5 7 7	12/26/95	Sackler, et al.	424	489		
								6 1 4 3 3 2 2	11/07/00	Sackler, et al.	424	459		
								5 9 5 8 4 5 9	09/28/99	Chasin, et al.	424	490		
								6 1 0 3 2 6 1	08/15/00	Chasin, et al.	424	459		
<b>FOREIGN PATENT DOCUMENTS</b>														
													TRANSLATION	
													YES	NO
								0 3 7 7 5 1 8	11/07/90	EPO (A3)	A61K	9/52		
								WO 94 0 3 1 6 0	02/17/94	PCT	A61K	9/32		
								0 3 7 7 5 1 8	11/07/90	EPO (A2)	A61K	9/52		
								0 3 2 7 2 9 5	08/09/89	EPO (A2)	A61K	9/52		
								0 6 3 6 3 7 0	02/01/95	EPO (A1)	A61K	31/485		
								2 0 8 2 5 7 3	11/10/92	Canada	A61K	047/38		
<b>OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)</b>														
	GN	R.K. Kaiko, "The Pre-and Postoperative Use of Controlled-Release Morphine (MS Contin Tablets): A Review of the Published Literature," Medical Department, The Purdue Frederick Company, Royal Society of Medical Services, International Congress, Symposium Services, No. 149, pp. 147-160 (1989).												
	GO	H.F. Slowey et al., "Effect of Premedication with Controlled-Release Oral Morphine on Postoperative Pain," Anaesthesia, 1985, Vol. 40, pp. 438-40.												
	GP	MS Contin - Frequency of Daily Dosing, January - November 1990												
	GQ													
	GR													
	GS													
	GT													
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*EXAMINER INITIAL		DOCUMENT NUMBER						DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE		
	HA													
	HB													
	HC													
	HD													
	HE													
	HF													
	HG													
	HH													
<b>FOREIGN PATENT DOCUMENTS</b>														
		DOCUMENT NUMBER						DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION		
												YES	NO	
	HI	2	1	3	1	3	5	0	01/09/94	Canada (A1)	A61K	031/135		
	HJ	0	1	0	8	2	1	8	05/16/84	EPO (A2)	A61K	9/22		
	HK	0	1	4	7	7	8	0	07/10/85	EPO (A2)	A61K	9/32		
	HL													
	HM													
<b>OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)</b>														
	HN	R.K. Portenoy, et al., "A Randomized, Double-Blind, Double-Dummy, Crossover Study Comparing the Pharmacokinetics and Pharmacodynamics of Kapanol® Capsules Given Every 24 hours and Every 12 hours with MS Contin® Tablets Given Every 12 Hours in the Management of Patients with Moderate to Severe Chronic Pain" Memorial Hospital IRB Protocol pp. 379-381												
	HO	7 <sup>th</sup> World Congress on Pain, Abstracts 997-1001, August 26, 1993.												
	HP	Advertisement: Roxanol SR., 1988 Roxane Labs, Inc.												
	HQ	T. Hunt and R. Kaiko, Comparison of the Pharmacokinetic Profiles of Two Oral Controlled-Release Morphine Formulation in Healthy Young Adults, Clin. Thera., Vol. 13, No. 4, pages 482-488, 1991												
	HR	S. Bloomfield, et al. Analgesic Efficacy and Potency of Two Oral Controlled-Release Morphine Preparations Clin. Pharmacol. Ther., Vol. 53, No.4, pages 469-478, 1993												
	HS	Advertisement: MS Contin 1986, 1987 The Purdue Frederick Company.												
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*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	IA	4	9	3	5	2	4	6	06/19/90	Ahrens	424	490		
	IB	2	7	3	8	3	0	3	03/13/56	Blythe	167	82		
	IC	5	0	7	6	5	6	0	06/25/91	Makino, et al.	424	494		
	ID	5	1	3	2	1	4	2	07/21/92	Jones, et al.	427	196		
	IE	3	9	1	6	8	8	9	11/04/75	Russell	128	145.8		
	IF	4	0	8	8	8	6	4	05/09/78	Theeuwes, et al.	219	121 LM		
	IG	4	0	6	3	0	6	4	12/13/77	Saunders, et al.	219	121 L		
	IH	4	1	3	2	7	5	3	01/02/79	Blichare, et al.	264	25		
	II	4	4	2	1	7	3	6	12/20/83	Walters	424	19		
	IJ	4	8	9	4	2	3	4	01/16/90	Sharma, et al.	424	440		
	IK	5	0	2	3	0	8	9	06/11/91	Sakamoto, et al.	424	502		
FOREIGN PATENT DOCUMENTS														
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	IL	WO	93	0	7	8	6	1	04/29/93	PCT (A1)	A61K	9/50		
	IM	WO	92	0	2	2	0	9	02/20/92	PCT (A1)	A61K	9/22	(Abstract)	
	IN	WO	93	0	7	8	5	9	04/29/93	PCT (A1)	A61K	9/16		
	IO	0	2	6	7	7	0	2	05/18/88	EPO (A3)	A61K	9/14		
	IP	0	3	6	1	6	8	0	04/04/90	EPO (B1)	A61K	9/46		
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)														
	IQ	Sustained Release Medications, Noyes Data Corp., pages 3,4,10-15, 96-99, 335-337 (1980).												
	IR	Flanders, P., et al. "The Control of Drug Release From Conventional Melt Granulation Matrices," <u>Drug Development and Industrial Pharmacy</u> , Vol. 13, No. 6, pp. 1001-1022 (1987).												
EXAMINER										DATE CONSIDERED				
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JA	5 0 3 0 4 0 0	07/09/91	Danielsen, et al.	264	101		
JB	5 1 2 6 1 4 5	06/30/92	Evenstad, et al.	424	465		
JC	5 1 9 6 2 0 3	03/23/93	Boehm	424	469		
JD	5 2 9 2 4 6 1	03/08/94	Juch, et al.	264	37		
JE	5 1 6 7 9 6 4	12/01/92	Muhammed, et al.	424	482		
JF	4 4 4 3 4 2 8	04/17/84	Oshlack, et al.	424	22		
JG	5 6 1 4 2 1 8	03/25/97	Olsson, et al.	424	456		
JH	5 6 2 9 0 1 1	05/13/97	Illum	424	434		
JI	4 4 6 4 3 7 8	08/07/84	Hussain	424	260		
JJ	5 5 0 2 0 5 8	03/26/96	Mayer, et al.	514	289		
<b>FOREIGN PATENT DOCUMENTS</b>							
	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
JK	0 3 6 1 9 1 0	04/04/90	EPO (A1)	A61K	9/16		
JL	0 3 7 7 5 1 7	07/11/90	EPO (A2)	A61K	31/52		
JM	0 4 3 0 2 8 7	06/05/91	EPO (B1)	A61K	9/54		
JN	0 4 5 2 1 4 5	10/16/91	EPO (A2)	A61K	9/14		
JO	0 5 5 3 3 9 2	08/04/93	EPO (A1)	A61K	9/50		
JP	0 5 3 3 2 9 7	03/24/93	EPO (A1)	A61K	9/16		
<b>OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)</b>							
JQ	McTaggart, Celia M., et al., "The evaluation of formulation and processing conditions of a melt granulation process," International Journal of Pharmaceutics, Vol. 19, pp. 139-148 (1984)						
JR	Schaefer, T., et al., "Melt granulation in a laboratory scale high shear mixer," <u>Drug Development and Industrial Pharmacy</u> , Vol. 16, No. 8, pp. 1249-1277 (1990)						
JS	Thomsen, L. Juul, et al., "Prolonged Release Matrix Pellets Prepared by Melt Pelletization I. Process Variables," <u>Drug Development and Industrial Pharmacy</u> , Vol. 19, No. 15, pp. 1867-1887 (1993)						
JT	Thomsen, L. Juul, "Prolonged Release Matrix Pellets prepared by Melt Pelletization II. Hydrophobic Substances as Melttable Binders Vol. 20, No. 77, pp.1179-1197 (1994)						
EXAMINER				DATE CONSIDERED			
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*EXAMINER INITIAL		DOCUMENT NUMBER			DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE		
	KA										
	KB										
	KC										
	KD										
	KE										
	KF										
	KG										
	KH										
	KI										
	KJ										
FOREIGN PATENT DOCUMENTS											
		DOCUMENT NUMBER			DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION		
									YES      NO		
	KK	0	6	0	9 9 6 1	08/10/94	EPO (A1)	A61K	31/485		
	KL	0	6	3	6 3 7 0	02/01/95	EPO (A1)	A61K	31/485		
	KM	2	0	5	3 6 8 1	02/11/81	Great Britain (B)	A61K	9/22		
	KN	WO	92	0	8 4 5 9	05/29/92	PCT (A1)	A61K	31/485		
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)											
	KO	Thomsen, L. Juul, "Utilizing melt pelletization technique for the preparation of prolonged release products," <u>Pelletization</u> , (material elaborated by assistant prof. Lars Juul Thomsen, Department of Pharmaceutics, Royal Danish School of Pharmacy for the DIE course "Pelletization Technolohg," November 1992, 106 pages plus 3 appendices									
	KP	Thomsen, L. Juul, "Prolonged Release Matrix Pellets Prepared by Melt Pelletization. Part IV: Drug Particles Size, and Binder Composition," : <u>Pharmaceutical Technology Europa</u> , pp. 19-24 (October 1994)									
	KQ	Maccarrone C. et al.; "Single Dose Pharmacokinetics of Kapanol™, a New Oral Sustained-Release Morphine Formulation; <u>Clinical Drug Investigation</u> 1994:7 (5) 262-274									
	KR	West R. J., et al., "Single dose pharmacokinetics of a new oral sustained release morphine formulation, Kapanol™ capsules," (Abstract 997) International Association for the Study of Pain, 7 <sup>th</sup> World Congress on Pain. Paris, August 22-27, 1993 (Data on file, Glaxo Australia, F.H. Faulding)									
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	LA													
	LB													
	LC													
	LD													
	LE													
	LF													
	LG													
	LH													
<b>FOREIGN PATENT DOCUMENTS</b>														
		DOCUMENT NUMBER				DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION				
										YES	NO			
	LI	04	0	8	1	0	8	6	04/02/92	Japan	A61K	9/10	X	
	LJ													
	LK													
<b>OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)</b>														
	LL	Gourlay GK, et al., "A comparison of Kapanol™ (A new sustained release morphine formulation), MST Continus® and morphine solution in cancer patients: pharmacokinetics aspects." (Abstract 998) International Association for the Study of Pain, 7 <sup>th</sup> World Congress on Pain Paris, August 22-27, 1993 (Data on file, Glaxo Australia, F.H. Faulding)												
	LM	Cherry DA, et al., "A comparison of Kapanol™ (a new sustained release morphine formulation), MST Continus® and morphine solution in cancer patients: Morphine metabolite profiles and renal function." (Abstract 999) International Association for the Study of Pain, 7 <sup>th</sup> World Congress on Pain, Paris August 22-27, 1993 (Data on file, Glaxo Australia, F.H. Faulding)												
	LN	Plummer JL, et al., "A comparison of Kapanol™ (a new sustained release morphine formulation) MST Continus® and morphine solution in cancer patients: pharmacodynamic aspects." (Abstract 1000) International Association for the Study of Pain, 7 <sup>th</sup> World Congress on Pain, Paris, August 22-27, 1993 (Data on file, Glaxo Australia, F.H. Faulding)												
	LO	Toner G, Cramond T, Bishop, et al., "Randomized double blind, phase III crossover study of a new sustained-release oral morphine formulation, Kapanol™ capsules", (Abstract 1001) International Association for the Study on Pain, Paris, August 22-27, 1993 (Data on file, Glaxo Australia, F.H. Faulding)												
	LP	Cherry DA, et al., "Once A Day (i.e. 24 Hourly) Kapanol™, A New Sustained Release Morphine Formulation, in the Treatment of Cancer Pain: Morphine Metabolite Profiles"; European Journal of Cancer; Part A General Topics 1995; 31 (S5) Suppl:S184 Abs 884, European Conference on Clinical Oncology and Cancer Nursing, Paris, 29 Oct-2 Nov 1995.												
							DATE CONSIDERED							
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	MA	5	8	4	3	4	8	0	12/01/98	Miller, et al.	424	484		
	MB	5	8	4	9	2	4	0	12/15/98	Miller, et al.	264	460		
	MC	5	8	7	9	7	0	5	03/09/99	Heafield, et al.	424	464		
	MD	5	8	9	1	4	7	1	04/06/99	Miller, et al.	424	468		
	ME	5	9	6	5	1	6	3	10/12/99	Miller, et al.	424	468		
	MF	5	9	6	8	5	5	1	10/19/99	Oshlack, et al.	424	456		
	MG	5	1	3	3	9	7	4	07/28/92	Paradissis, et al.	424	480		
	MH	5	2	6	6	3	3	1	11/30/93	Oshlack, et al.	424	468		
	MI	5	6	5	6	2	9	5	08/12/97	Oshlack, et al.	424	468		
	MJ	5	6	7	0	1	7	2	09/23/97	Buxton, et al.	424	495		
	MK	5	6	7	2	3	6	0	09/30/97	Sackler, et al.	424	490		
	ML	5	6	8	1	5	8	5	10/28/97	Oshlack, et al.	424	494		
	MM	4	8	4	4	9	0	9	07/04/89	Goldie, et al.	424	480		
<b>FOREIGN PATENT DOCUMENTS</b>														
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	MN													
<b>OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)</b>														
	MO	Gourlay, et al., "Once A Day (i.e. 24 Hourly) Kapanol™, A New Sustained Release Morphine Formulation, In The Treatment of Cancer Pain: Pharmacokinetic Aspects", European Journal of Cancer; Part A General Topics 1995:31 (S5) Suppl: S187 Abs 897, European Conference on Clinical Oncology and Cancer Nursing, Paris, 29 Oct-2 Nov 1995												
	MP	Broomhead, et al. "Kadian™/Kapanol™-A Once Daily Morphine Formulation" European Journal of Cancer; Part A General Topics 1995:31 (S5) Suppl: S182 Abs 873, European Conference on Clinical Oncology and Cancer Nursing, Paris, 29 Oct-2 Nov 1995												
	MQ	Gourlay et al., Proceedings of the 7 <sup>th</sup> World Congress on Pain; A comparison of Kapanol (a New Sustained-Release Morphine Formulation), MST Continus, and Morphine Solution in Cancer Patients: Pharmacokinetic Aspects of Morphine and Morphine Metabolites Progress in Pain Research and Management Volume 2 pp 631-643												
	MR	Kaiko R.F., "Clinical Protocol and Role of Controlled Release Morphine in the Surgical Patient," <u>Anesthesiology and Pain Management</u> 1991 pp 193-212												
	MS	MS Contin - Frequency of Daily Dosing (NDTI) - June, 1991 - May, 1992												
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	NA													
	NB													
	NC													
	ND													
<b>FOREIGN PATENT DOCUMENTS</b>														
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	NE	0	5	3	2	3	4	8	03/17/93	EP (A3)	C07C	291/04		
	NF	0	5	3	2	3	4	8	03/17/93	EP (B1)	C07C	291/04		
	NG	0	5	3	4	6	2	8	03/31/93	EP (B1)	A61K	31/485		
	NH	0	2	5	3	1	0	4	01/20/88	EPO (B1)	A61K	9/00		
	NI	0	2	3	5	9	8	6	09/09/87	EPO (B1)	A61K	9/16		
	NJ	0	2	3	5	9	8	6	09/09/87	EP (B2)	A61K	9/16		
	NK	0	3	7	7	5	1	8	07/11/90	EPO (A3)	A61K	9/52		
	NL	0	3	8	8	9	5	4	09/26/90	EPO (A3)	A61K	9/14		
	NM	0	3	8	8	9	5	4	09/26/90	EPO (B1)	A61K	9/14		
	NN	0	0	9	7	5	2	3	01/04/84	EPO (B1)	A61K	9/26		
<b>NPHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)</b>														
	NQ													
EXAMINER										DATE CONSIDERED				
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.														

FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE				ATTY. DOCKET NO.: 200.1138 US		SERIAL NO.: 10/016,651						
<b>LIST OF PRIOR ART CITED BY APPLICANT</b> (Use several sheets if necessary)						APPLICANT(S): Benjamin OSHLACK, et al.								
						FILING DATE: October 30, 2001		GROUP: 1615						
<b>U.S. PATENT DOCUMENTS</b>														
*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	AA	5	8	6	6	1	6	1	02/02/1999	Childers, et al.	424	465		
	AB	6	4	9	1	9	4	5	12/10/2002	Childers, et al.	424	465		
	AC													
	AD													
	AE													
	AF													
	AG													
	AH													
	AI													
	AJ													
	AK													
<b>FOREIGN PATENT DOCUMENTS</b>														
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	AL													
	AM													
	AN													
	AO													
	AP													
	AQ													
<b>OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)</b>														
	AR													
	AS													
	AT													
EXAMINER										DATE CONSIDERED				
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.														